

MAR 17 1986

Re: Cefotan Docket No. 86E-0098 Food and Drug Administration
Rockville MD 20857
RECEIVED IN
DIRECTOR'S OFFICE

MAR 20 1986

Mr. Charles E. Van Horn Director, Patent Examining Group 120 U.S. Patent and Trademark Office Washington, DC 20231

GROUP 120

Dear Mr. Van Horn:

This is in regard to the application for patent term restoration for U.S. Patent No. 4,263,432, filed by Yamanouchi Pharmaceutical Co., Ltd., under the patent term restoration provisions of 35 U.S.C. 156. The human drug product claimed by the patent is Cefotan (cefotetan disodium), New Drug Application (NDA) 50-588.

A review of the Food and Drug Administration's official records indicates that Cefotan, the product identified in the patent term restoration application, was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4). Our records also indicate that NDA 50-588 represents the first permitted commercial marketing or use of the active ingredient, cefotetan disodium. The NDA was approved on December 27, 1985 which makes the submission of the patent term restoration application on February 21, 1985 timely within 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent term restoration, please advise us accordingly. As required by 35 U.S.C. 156(d)(2)(A), we will then determine the applicable regulatory review period, publish that determination in the <u>Federal Register</u>, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Ronald L. Wilson

Director

Health Assessment Policy Staff

Office of Health Affairs

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